



Rubella Vaccination Campaigns in Brazil, Impact on Induced Abortions

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**FROM AUGUST 9TH TO SEPTEMBER 15TH
BRAZILIAN 2008 CAMPAIGN**



**TO VACINADO
BRASIL LIVRE DA RUBEOLA**

BRASIL LIVRE DA RUBÉOLA

SE VOCÊ TEM ENTRE 20 E 39 ANOS, VACINE-SE! E SE VOCÊ MORA NOS ESTADOS DO MA, MG, RJ, RN E MT, A IDADE É DE 12 A 39 ANOS

Secretarias Estaduais e Municipais de Saúde SUS Ministério da Saúde GOVERNO FEDERAL



HISTORY OF RUBELLA VACCINATION IN BRAZIL

1992 – 2000

GRADUAL VACCINATION IMPLANTATION

MEASLES-MUMPS-RUBELLA

**CHILDREN 1 – 11 YEARS OLD
AND**

WOMEN: POST PARTUM, POST ABORTION AND CAMPAIGNS

2001

**CAMPAIGN IN 13 BRAZILIAN STATES
WOMEN 15 – 29 YEARS OLD**

2002

**CAMPAIGN IN 11 BRAZILIAN STATES
WOMEN 15 – 29 YEARS OLD**

2008

**NATIONAL CAMPAIGN
WOMEN AND MEN 20 – 39 YEARS OLD
WOMEN AND MEN 15 -39 Y.O. IN 5 BRAZILIAN STATES**



2008 RUBELLA CAMPAIGN

70.000.000 PEOPLE VACCINATED:

35.300.000 WOMEN

34.700.000 MEN

0.23% MAY BE PREGNANT
(Minussi et al. 2007)

82,654 PREGNANT WOMEN

5% OF TOP AFTER
COUNSELING IN
RIO DE JANEIRO TIS

4,133 TOP



- It is hard to convince the pregnant women that there is no reason to consider termination of pregnancy.
- Probably the rate of TOP among inadvertently vaccinated pregnant women in the general population will be higher than that among the counseled women of TIS.
- The rubella vaccine label, the campaign orientation to not vaccinate pregnant women or to avoid pregnancy until one month after rubella vaccination, and misinformation among doctors were the main reasons presented to explain the rate of TOP in a country where it is forbidden by law.



Rubella Vaccine

Bar-Oz et al., 2004

- The attenuated rubella-vaccine virus has been shown to cross the placenta and was found in products of conception as well as in the uterine cervix.
- Due to the potential fetal hazards of the live virus, the label states explicitly that the vaccine is contraindicated in pregnancy or within 3 months prior to conception.
- Unfortunately, this strong labeling is interpreted by physicians and patients as proven evidence of teratogenicity.

Congenital infection in the newborn is well proved,
occurring in about 5% of the exposed

- Phillips et al., 1970
- Vaheri et al., 1972
- Bolognese et al., 1973
- Ebbin et al., 1973
- Wyll and Herrmann, 1973
- Fleet et al., 1974
- Hayden et al., 1980
- Bart et al., 1985
- Enders et al., 1985
- Sheppard et al., 1986
- Preblud et al., 1987
- MMWR 1989
- CDC / MMWR 2001
- Hankar et al., 2006
- Minussi et al., 2008

However no case of CRS was described until now



Minussi et al., 2008

Maximum theoretical risk of congenital rubella syndrome from the vaccine, considering the studies available in the literature

Studies	<i>N</i>	CRS	Wilson's score-test [16]	
			95% of confidence	99% of confidence
MMWR [13]	272	0	1.4	2.4
Bar-Oz et al. [17]	94	0	3.9	6.6
Hamkar et al. [18]	117	0	3.2	5.4
Present study	423	0	0.9	1.5
Sum total	906	0	0.4	0.7



PubMed search

- Rubella vaccine AND Pregnancy : 952 papers
- Risk AND Rubella vaccine : 608 papers
- Fetal risk AND Rubella vaccination : 47 papers

- Only 3 papers presented follow-up of inadvertently vaccinated pregnant women and controls

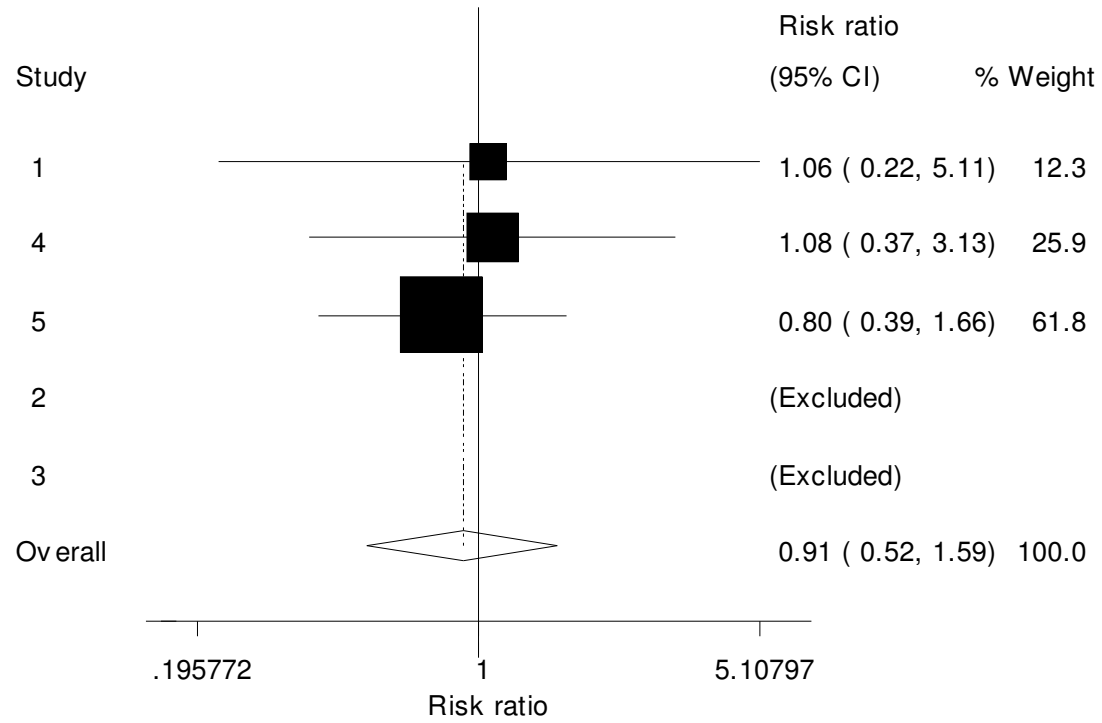


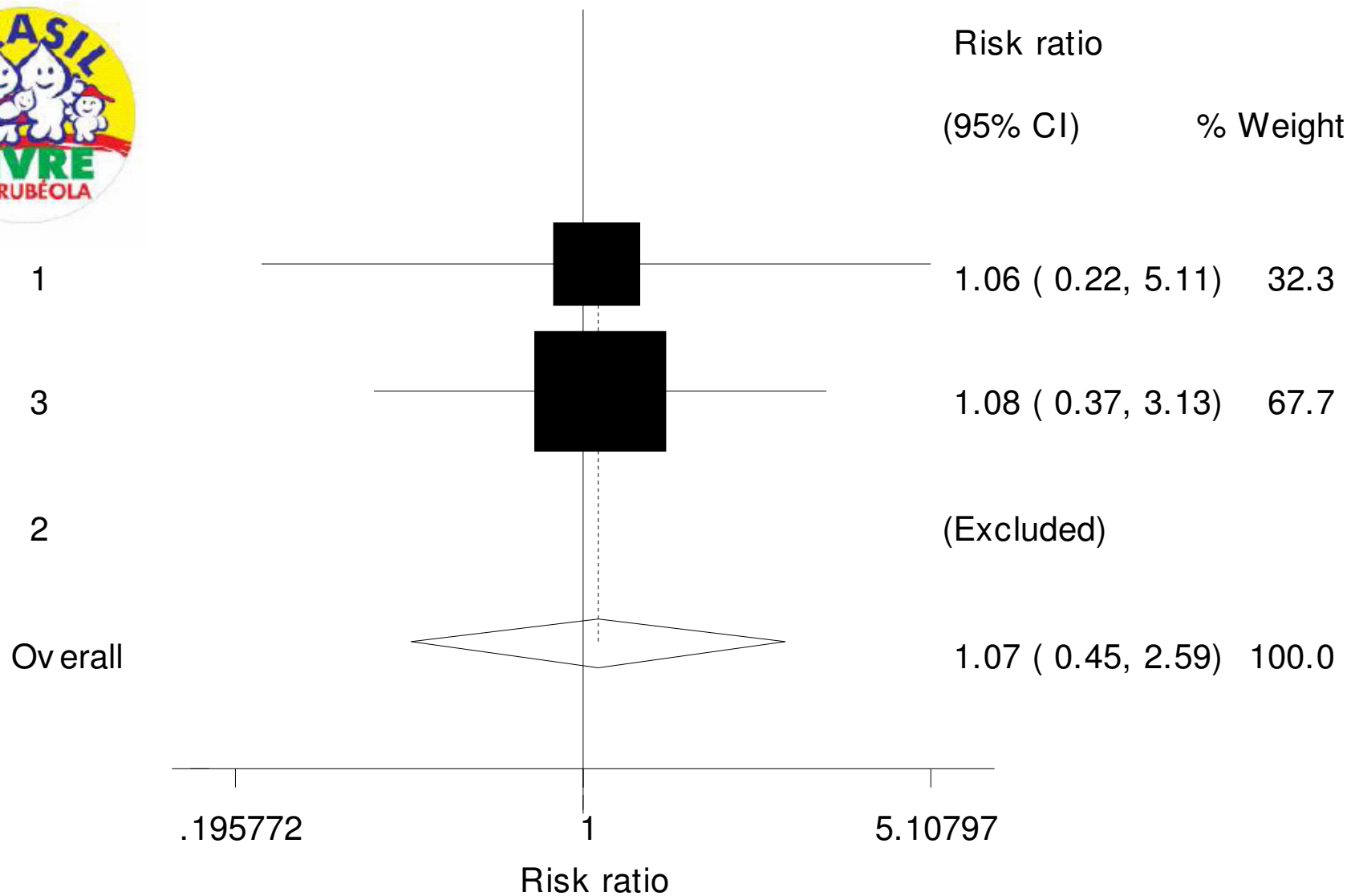
Reference	Cases		Controls	
	Malf	N_malf	Malf	N_malf
• Bar-Oz et al. 2004	3	79	3	84
• Sá et al. 2006	0	216	0	316
• Badilla et al. 2007	5	88	9	172
•				
• Badilla et al. 2007 *	31	744	9	172
• Sá et al. 2006*	0	1576	0	316



References	Cases		Controls		
	Malf	Nmalf	Malf	Nmalf	
Bar-Oz et al. 2004	3	79	3	84	exposed to non-teratogenic drugs
Sá et al. 2006	0	216	0	316	(-) for IgM, (+) for IgG
Badilla et al. 2007	5	88	9	172	(-) for IgM, (+) for IgG
	Compatible with CRS*				
Sá et al. 2006	0	1576	0	316	
Badilla et al. 2007	31	744	9	172	
	immune status unknown				

*Includes hearing impairment, retinopathy, congenital heart disease, hepatosplenomegaly, microcephaly, jaundice, developmental delay, and low birth weight.







Badilla et al., 2007

- Because the evidence of risk from the rubella vaccination to the fetus is theoretical, the main reason for not recommending the vaccine to pregnant women is to avoid its implication in adverse events during the pregnancy that are not related to the vaccine itself.



- While rubella vaccination is “contraindicated” during pregnancy by the accompanying leaflet, TOP is not justified when vaccination occurs during an unrecognized pregnancy.
- How to convincingly conciliate contraindication with low risk is the main challenge during counseling patients or support obstetricians at a TIS (Teratogenic Information Service).